510(k) SUMMARY
Zimmer Spine Sequoia® Pedicle Screw System including
SpeedLink II™ Transverse Connector System

Date of Summary Preparation:	August 29, 2013
Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439
Establishment Registration Number:	2184052
Company Contact:	Jonathan Gilbert Regulatory Affairs Director Email: jonathan.gilbert@zimmer.com Office: 952.830.6385 Fax: 952.837.6985
Trade Name:	Zimmer Spine Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System
Device Name (Common Name): Disease;	Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Orthosis, Spondylolisthesis Spinal Fixation; Orthosis, Spinal Pedicle Fixation
Device Classification:	Class III and Class II
Product Code(s):	NKB, MNH, MNI
Regulation Number:	21 CFR §888.3070
Regulation Description:	Pedicle screw spinal system

SEP 0 4 2013

Predicate Devices:

For clarification purposes, this is the initial submission for this device modification and has not previously been submitted/withdrawn via a 510(k), PMA or de novo pathway. The modified Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System is claimed to be substantially equivalent to the following legally marketed predicate devices:

Sequoia® Pedicle Screw System Predicate Device Name	Submission ID Number	Clearance Date
Sequoia® Pedicle Screw System including Speedlink Transverse Connector System	K082032	October 6, 2008
Modification To Incompass Spinal Fixation System	K023644	November 25, 2002
Synergy D2 Spinal Implants	K984578	March 23, 1999
Titanium TSRH(R) Spinal System (Screws)	K946348	August 7, 1995

General Device Description:

The Sequoia® Pedicle Screw System is designed to aid in the surgical correction of several types of spinal conditions (see indications below). This system is intended only to provide stabilization during the development of a solid fusion with a bone graft. These implants are intended to be removed after the development of a solid fusion mass.

The Sequoia® Pedicle Screw System consisting of open style polyaxial screws, titanium rods (varying lengths) and connectors is intended to provide temporary stabilization following surgery to fuse the spine. The polyaxial screw design allows the surgeon to use a top-loading technique for dropping the spinal rod down to the fixation components into a u-shaped opening.

SpeedLink II ™ Transverse Connectors are provided to increase rotational stiffness to the final construct.

Indications for Use:

When intended for pedicle screw fixation from T1 -S1, the Sequoia® Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

As a pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after the solid fusion is established.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine (T1-S1), the indications are idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degenerative of the disc confirmed by history and radiographic studies), tumor, spondylolisthesis, spinal stenosis and failed previous fusion.

Summary of Technological Characteristics:

The current Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System shares the same technological characteristics as the predicate device Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System. The characteristics include the same design, same materials, and same range of sizes, substantially equivalent performance characteristics and a subset of the indication for use.

The current and predicate Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System both consist of open style polyaxial screws, titanium rods, connectors and the instruments/accessories necessary to implant the spinal system. All implant components are made from a titanium alloy (Ti-6Al-4V) and Unalloyed Titanium (CP Ti).

The Sequoia® Pedicle Screw System is designed to aid in the surgical correction of several types of spinal conditions, as stated in the section above. The Sequoia® Pedicle Screw System consisting of open style polyaxial screws, titanium rods and connectors is intended to provide temporary stabilization following surgery to fuse the spine. The polyaxial screw design allows the surgeon to use a top-loading technique for dropping the spinal rod down to the fixation components into a u- shaped opening. The use of the SpeedLine II™ Transverse Connectors as a construct component during implementation of the Sequoia® Pedicle Screw System is at the discretion of the surgeon and is not required. This system is intended only to provide stabilization during the development of a solid fusion with a bone graft. These implants are intended to be removed after the development of a solid fusion mass. The current and predicate systems are provided non-sterile, are for single use only and are intended to be removed after solid fusion has occurred.

Summary of Performance Testing:

The Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System is substantially equivalent to the predicate devices in design, materials, function and intended use.

The performance testing included components of the current Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System, which were reviewed and tested appropriately for design verification, design validation, biocompatibility and sterilization. The test results conclude the current Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System to be substantially equivalent to their predicate devices, Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System.

- Bench testing (static compression bending, dynamic compression bending, and static torsion testing per ASTM F1717 & F1798 as applicable) for implants, polyaxial screws, titanium rods, and connectors, confirmed the product performance of the current Sequoia® Pedicle Screw System including SpeedLink II ™Transverse Connector System is suitable for its intended use.
- Cadaver lab testing of the current Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System to evaluate human factors regarding the combination of instrument design changes and labeling design changes, as well as interaction with implants to confirm the substantial equivalence of the changes compared to the identified predicate devices.
- Biocompatibility testing ensured the current Sequoia® Pedicle Screw System including SpeedLink II ™Transverse Connector System materials are biocompatible after manufacturing based on the minor design changes made in comparison to the predicate devices.
- Sterilization, Dry Time and Cleaning testing ensured the current Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System steam sterilization, cleaning and dry time instructions *are* substantially equivalent to the predicate devices.

Substantial Equivalence:

Zimmer Spine considers the current Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System product performance to be substantially equivalent to their cleared predicate device, Sequoia® Pedicle Screw System including SpeedLink II ™Transverse Connector System because there are no changes to the product performance specifications or device functional scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 4, 2013

Zimmer Spine, Incorporated
Mr. Jonathan Gilbert
Regulatory Affairs Director
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K131980
Trade/Device Name: Zimmer Spine Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System.
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: July 5, 2013
Received: July 8, 2013

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131980

Device Name: Zimmer Spine Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System

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Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-the Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131980